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10/550,528	11/27/2006	Naohiko Hirota	278432US0PCT	3047

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EXAMINER
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RAGHU, GANAPATHIRAM

ART UNIT	PAPER NUMBER
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1652

NOTIFICATION DATE	DELIVERY MODE
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05/27/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/550,528	<b>Applicant(s)</b> HIROTA ET AL.	
	<b>Examiner</b> GANAPATHIRAMA RAGHU	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-13 is/are allowed.
- 6) ☒ Claim(s) 1-9 and 14-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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***Application Status***

In response to the Office Action mailed on 12/18/09, applicants' response filed on 03/16/10 is acknowledged. In said response applicants' have amended claims 1-13 and added new claims 14-17. Claims 1-17 are pending in this application and are now under consideration.

Objections and rejections not reiterated from previous action are hereby withdrawn.

***Withdrawn-Claim Rejections 35 USC § 101***

Previous rejection of claims 1, 2 and 10-12 rejected under 35 U.S.C. 101, is being withdrawn due to claim amendments.

***Withdrawn-Claim Rejections 35 USC § 112-Second Paragraph***

Previous rejection of claim 9 rejected under 35 U.S.C. 112, second paragraph, is being withdrawn due to claim amendment.

***In the Claims***

Claims 7-9 and 14-17 recite "derived", examiner suggests amending the claims to recite "obtained". Appropriate correction is required.

***Maintained-Double Patenting rejection***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-9 and 14-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-9 and 14-17 of co-pending application 12/505,723 (Hirota et al.). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over reference claim. See, e.g., *In re Berg*, 140 F.3d 1428,46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir.1993); *In re Longi* 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985). Although, the conflicting claims are not identical, they are not patentably distinct from each other. Claims 7-9 and 14-17 of the instant application cannot be considered patentably distinct over claims 7-9 and 14-17 of co-pending application 12/505,723 (Hirota et al.), when there is specifically disclosed embodiment that supports claims 7-9 and 14-17 of co-pending application 12/505,723 (Hirota et al.) and falls within the scope of the claims 7-9 herein. In the instant case the specification of co-pending application 12/505,723 (Hirota et al.) discloses as a preferred embodiment; a product produced from a barley plant wherein the barley plant has mutation in the LOX-1 gene causing a total loss of LOX-1 activity. Therefore, the invention of claims 7-9 and 14-17 of the instant invention are deemed an obvious

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variation of the invention of claims 7-9 and 14-17 of co-pending application 12/505,723 (Hirota et al.,).

*In support of their request that the prior rejection of claims 7-9 and 14-17 that are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-9 and 14-17 of co-pending application 12/505,723 (Hirota et al.,) be withdrawn, applicants' provide the following argument (see pages 7-8 of applicants' REMARKS/ARGUMENTS dated 03/16/10).*

"...in accord with MPEP 882.01, if the "provisional" double patenting rejection in present application is the only rejection remaining, the examiner should then withdraw that rejection and permit the present application to issue as a patent..."

**Reply:** Applicants' arguments have been considered but are found to be non-persuasive, claims 7-9 and 14-17 continue to stand rejected as they are not ready for allowance and thus examiner is maintaining the rejection.

***Maintained-Claim Rejections: 35 USC § 112-First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

***Enablement***

Claim 1 and claims 2-9 and 14-17 depending therefrom is rejected under 35 U.S.C. 112, first paragraph. The specification is enabling for an isolated barley lipoxygenase-1 (LOX-1) mutant comprising the polynucleotide sequence of SEQ ID NO: 10 corresponding to the coding region of said mutant LOX-1 and encoding a polypeptide having completely deficient LOX-1 activity (paragraph [0018] of

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specification) and the corresponding genomic region of said mutant LOX-1 comprising the polynucleotide sequence of SEQ ID NO: 11 (paragraph [0019] of specification), and a selection method for a barley comprising said polynucleotide sequences i.e., SEQ ID NO: 10 and 11, said selection method comprising amplification of said genomic sequences and the detection of restriction length polymorphisms (RFLP) by digesting the amplified genomic DNA with restriction enzymes *AfaI* and/or *RsaI* from said barley plants comprising the specific mutant LOX-1 gene and further a process for production of alcoholic beverages from said barley plant comprising specific mutant LOX-1 gene. However, the specification does not reasonably provide enablement for any variant or mutant barley LOX-1 gene of undefined structure and a selection method for a barley comprising any variant or mutant LOX-1 gene/DNA and encoding a polypeptide with deficient LOX-1 activity ("deficient" is a relative term and the term "deficient" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention), said selection method comprising amplification of said genomic sequence and detection of undefined restriction length polymorphisms (RFLP) by digesting said amplified genomic DNA with any restriction enzyme or with restriction enzymes *AfaI* and/or *RsaI* from said barley plants comprising said mutant LOX-1 gene of undefined structure, a seed, a malt, barley decomposition product derived by said selection process and further a process for production of alcoholic beverages from said barley plant comprising variant or mutant LOX-1 gene of undefined structure. The specification does not enable any person skilled in the art to which it pertains, or with

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which it is most nearly connected, to use the invention commensurate in scope with the claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1-9 and 14-17 are so broad as to encompass any variant or mutant barley LOX-1 gene of undefined structure and a selection method for a barley comprising any variant or mutant LOX-1 gene/DNA and encoding a polypeptide with deficient LOX-1 activity ("deficient" is a relative term and the term "deficient" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention), said selection method comprising amplification of said genomic sequence and detection of undefined restriction length polymorphisms (RFLP) by digesting said amplified genomic DNA with any restriction enzyme or with restriction enzymes *AfaI* and/or *RsaI* from said barley plants comprising said mutant LOX-1 gene of undefined structure, a seed, a malt, barley decomposition product derived by said selection process and further a process for production of alcoholic beverages from said barley plant comprising variant or mutant LOX-1 gene of undefined structure. The scope of the

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claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides and encoded polypeptides broadly encompassed by the claims. Since the amino acid sequence of a protein encoded by a polynucleotide determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires knowledge and guidance with regard to which amino acids in the protein's sequence and the respective codons in its polynucleotide, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the encoded proteins' structure relates to its function. However, in this case the disclosure is limited to an isolated barley lipoxygenase-1 (LOX-1) mutant comprising the polynucleotide sequence of SEQ ID NO: 10 corresponding to the coding region of said mutant LOX-1 and encoding a polypeptide having completely deficient LOX-1 activity (paragraph [0018] of specification) and the corresponding genomic region of said mutant LOX-1 comprising the polynucleotide sequence of SEQ ID NO: 11 (paragraph [0019] of specification), and a selection method for a barley comprising said polynucleotide sequences i.e., SEQ ID NO: 10 and 11, said selection method comprising amplification of said genomic sequences and the detection of restriction length polymorphisms (RFLP) by digesting the amplified genomic DNA with restriction enzymes *AfaI* and/or *RsaI* from said barley plants comprising the specific mutant LOX-1 gene and further a process for production of alcoholic beverages from said barley plant comprising specific mutant LOX-1 gene.



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While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is not routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claim, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable (for example, see Whisstock et al., 2003). In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions or deletions.

The specification does not support the broad scope of the claims 1-9 and 14-17 which encompasses any variant or mutant barley LOX-1 gene of undefined structure and a selection method for a barley comprising any variant or mutant LOX-1 gene/DNA and encoding a polypeptide with deficient LOX-1 activity ("deficient" is a relative term and the term "deficient" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention), said selection method comprising amplification of said genomic sequence and detection of undefined restriction length polymorphisms (RFLP) by digesting said amplified genomic DNA with any restriction enzyme or with restriction enzymes *AfaI* and/or *RsaI* from said barley plants comprising said mutant LOX-1 gene of undefined structure, a seed, a malt, barley decomposition product derived by said selection process and further a process for production of alcoholic beverages from said barley plant comprising variant or mutant

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LOX-1 gene of undefined structure. The specification does not enable the full scope of claims, because the specification does not establish: (A) the structure of all LOX-1 gene including variants, mutants and recombinants wherein the splicing donor site of the 5 th intron is mutated and encoding a "deficient" LOX-1; (B) the general tolerance of the polypeptide and the polynucleotide encoding LOX-1 to said modification and extent of such tolerance; (C) a rational and predictable scheme for said modification with any amino acid residue or the respective codon in the polynucleotide with an expectation of obtaining the desired biological function "deficient" LOX-1 activity; (D) defined core regions/motifs involved in the desired catalytic activity of encoded polypeptide; (E) the tertiary structure of the molecule and folding patterns that are essential for the desired activity and tolerance to modifications; and (F) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants' have not provided sufficient guidance to enable one of ordinary skill in the art to use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including polynucleotides and encoded polypeptides of undefined structure with an enormous number of modifications. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any variant or mutant barley LOX-1 gene of undefined structure and a selection method for a barley comprising any variant or mutant LOX-1 gene/DNA and encoding a polypeptide with deficient LOX-1 activity ("deficient" is a relative term and the term "deficient" is not

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defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention), said selection method comprising amplification of said genomic sequence and detection of undefined restriction length polymorphisms (RFLP) by digesting said amplified genomic DNA with any restriction enzyme or with restriction enzymes *AfaI* and/or *RsaI* from said barley plants comprising said mutant LOX-1 gene of undefined structure, a seed, a malt, barley decomposition product derived by said selection process and further a process for production of alcoholic beverages from said barley plant comprising variant or mutant LOX-1 gene of undefined structure, is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

*In support of their request that the prior rejection of claims 1-9 and 14-17 under 35 U.S.C. 112 for enablement be withdrawn, applicants' provide the following argument (see page 7 of applicants' REMARKS/ARGUMENTS dated 03/16/10).*

"...the examiner has misinterpreted that LOX-1 mutant gene of the present invention encodes a polypeptide having diminished LOX-1 activity...However, the present invention relates to LOX-1 mutant genes encoding a polypeptide with loss of LOX-1 activity..."

**Reply:** Applicants' arguments have been considered but are found to be non-persuasive. Claims are given the broadest interpretation and under this interpretation when there are no defined structural features or a reference to a parent sequence, the

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mutant LOX-1 gene can potentially have any number of structural features with no correlation to structure-function and claims as written also reads on yet to be discovered mutants, variants and alleles of barley LOX-1 gene with differing structures and function. Furthermore, "deficient" is a relative term and the term "deficient" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For these reasons, claims 1-9 and 14-17 stand rejected under 35 U.S.C. 112, first paragraph for enablement, as the scope and breadth of the claims encompasses many genes and encoded polypeptides with different structures lacking correlated function i.e., with desired phenotype and genotype and hence, the guidance provided by the art or the specification is in-sufficient, determination of gene and encoded polypeptides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

***Maintained-Written Description***

Claims 1-9 and 14-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the following reasons.

Claim 1-9 and 14-17 (as interpreted) are directed to any variant or mutant barley LOX-1 gene of undefined structure and a selection method for a barley comprising any

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variant or mutant LOX-1 gene/DNA and encoding a polypeptide with deficient LOX-1 activity ("deficient" is a relative term and the term "deficient" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention), said selection method comprising amplification of said genomic sequence and detection of undefined restriction length polymorphisms (RFLP) by digesting said amplified genomic DNA with any restriction enzyme or with restriction enzymes *AfaI* and/or *RsaI* from said barley plants comprising said mutant LOX-1 gene of undefined structure, a seed, a malt, barley decomposition product derived by said selection process and further a process for production of alcoholic beverages from said barley plant comprising variant or mutant LOX-1 gene of undefined structure.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species, which are adequately described, are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

There is no structure-function correlation with regard to the members of the genus of polynucleotides and encoded polypeptides as claimed in claims 1-9 and 14-17.

The specification discloses the structure of an isolated barley lipooxygenase-1 (LOX-1)

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mutant comprising the polynucleotide sequence of SEQ ID NO: 10 corresponding to the coding region of said mutant LOX-1 and encoding a polypeptide having completely deficient LOX-1 activity (paragraph [0018] of specification) and the corresponding genomic region of said mutant LOX-1 comprising the polynucleotide sequence of SEQ ID NO: 11 (paragraph [0019] of specification), and a selection method for a barley comprising said polynucleotide sequences i.e., SEQ ID NO: 10 and 11, said selection method comprising amplification of said genomic sequences and the detection of restriction length polymorphisms (RFLP) by digesting the amplified genomic DNA with restriction enzymes *AfaI* and/or *RsaI* from said barley plants comprising the specific mutant LOX-1 gene and further a process for production of alcoholic beverages from said barley plant comprising specific mutant LOX-1 gene of the claimed genus. The specification lacks description of any additional species i.e., any variant or mutant barley LOX-1 gene of undefined structure and a selection method for a barley comprising any variant or mutant LOX-1 gene/DNA and encoding a polypeptide with deficient LOX-1 activity ("deficient" is a relative term and the term "deficient" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention), said selection method comprising amplification of said genomic sequence and detection of undefined restriction length polymorphisms (RFLP) by digesting said amplified genomic DNA with any restriction enzyme or with restriction enzymes *AfaI* and/or *RsaI* from said barley plants comprising said mutant LOX-1 gene of undefined structure, a seed, a malt, barley decomposition product derived by said selection

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process and further a process for production of alcoholic beverages from said barley plant comprising variant or mutant LOX-1 gene of undefined structure by any relevant, identifying characteristics or properties or structure correlated with function and therefore one of skill in the art would not recognize from the disclosure that applicants' were in possession of the claimed invention. The art also teaches, even highly structurally homologous polynucleotides and encoded polypeptides do not necessarily share the same function and conversely functionally similar molecules do not necessarily have similar structures. For example proteins having similar structure have different activities; Witkowski et al., (Biochemistry 38:11643-11650, 1999) teaches that one conservative amino acid substitution transforms a  $\beta$ -ketoacyl synthase into a malonyl decarboxylase and completely eliminates  $\beta$ -ketoacyl synthase activity. Similarly, Wishart et al., (J. Biol. Chem., 1995, Vol. 270(10): 26782-26785) teach that a single mutation converts a novel phosphotyrosine binding domain into a dual-specificity phosphatase.

Hence, the recited genera of polynucleotides and encoded polypeptides are interpreted to have widely variable structures, since minor changes may result in changes affecting function and no additional information correlating structure with function has been provided.

Furthermore, "Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features" (See *University of Rochester*, 358 F.3d at 927, 69 USPQ2d at 1895).

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Therefore, given the lack of description of representative species encompassed by the genus of polynucleotides and encoded polypeptides and modifications, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Applicants are referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

*In support of their request that the prior rejection of claims 1-9 and 14-17 under 35 U.S.C. 112 for written description be withdrawn, applicants' provide the following argument (see page 6 of applicants' REMARKS/ARGUMENTS dated 03/16/10).*

"The barley LOX-1 gene is known in the art...The fact that LOX-1 with a known structure was within the knowledge of those skilled in the art, the specification and claims satisfy the written description requirement..."

**Reply:** Applicants' arguments have been considered but are found to be non-persuasive. Claims are given the broadest interpretation and under this interpretation when there are no defined structural features or a reference to a parent sequence, the mutant LOX-1 gene can potentially have any number of structural features with no correlation to structure-function and acclaims as written also reads on yet to be discovered mutants, variants and alleles of barley LOX-1 gene. Furthermore, "deficient" is a relative term and the term "deficient" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary



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skill in the art would not be reasonably apprised of the scope of the invention. For these reasons, claims 1-9 and 14-17 stand rejected under 35 U.S.C. 112, first paragraph for written description, as the scope and breadth of the claims encompasses many genes and encoded polypeptides with different structures lacking correlated function i.e., with desired phenotype and genotype

Furthermore, “A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does (function), rather what it is (structure)”, see *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938.

“Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features” (See *University of Rochester*, 358 F.3d at 927, 69 USPQ2d at 1895). Thus, claims as written lack adequate written description.

In addition:

1) The key focus of the argument is on the claims as written (see *In re Hinkler* 150 F.3d 1362, 1369, 47 USPQ2d 1523 (fed. Cir. 1998) and not proffered facts and are not commensurate with the breadth and scope of claims and therefore unpersuasive.

2) Although the claims are examined in the light of the specification, specification cannot be read into the claims, i.e., the limitations of the specification cannot be read into the claims (see MPEP 2111 R-5).

415 F.3d at 1316, 75 USPQ2d at 1329. See also *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969) (Claim 9 was directed to a process of analyzing data generated by mass

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spectrographic analysis of a gas. The process comprised selecting the data to be analyzed by subjecting the data to a mathematical manipulation. The examiner made rejections under 35 U.S.C. 101 and 102. In the 35 U.S.C. 102 rejection, the examiner explained that the claim was anticipated by a mental process augmented by pencil and paper markings. The court agreed that the claim was not limited to using a machine to carry out the process since the claim did not explicitly set forth the machine. The court explained that "reading a claim in light of the specification, to thereby interpret limitations explicitly recited in the claim, is a quite different thing from reading limitations of the specification into a claim, to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim." The court found that applicant was advocating the latter, i.e., the impermissible importation of subject matter from the specification into the claim.). See also *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997) (The court held that the PTO is not required, in the course of prosecution, to interpret claims in applications in the same manner as a court would interpret claims in an infringement suit. Rather, the "PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification."). The broadest reasonable interpretation of the claims must also be consistent with **the interpretation that those skilled in the art would reach.**

### ***Summary of Pending Issues***

The following is a summary of issues pending in the instant application.

1. Claims 7-9 and 14-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-9 and 14-17 of co-pending application 12/505,723 (Hirota et al.,).
2. Claims 1-9 and 14-17 depending therefrom is rejected under 35 U.S.C. 112, first paragraph, for enablement and written description.
3. Claims 10-13 are allowed.

### ***Conclusion***

Claims 1-9 and 14-17 are rejected for the reasons identified in the Rejections and Summary sections of this Office Action. Applicants' must respond to the rejections in each of the sections in this Office Action to be fully responsive for prosecution.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a).

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Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### ***Final Comments***

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached between 8 am-4: 30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ganapathirama Raghu/  
Patent Examiner  
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